

ATTITUDE MINERAL SUNSCREEN SENSITIVE SKIN CARE LITTLE ONES- zinc oxide cream
Bio Spectra

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

ATTITUDE®
Mineral sunscreen Sensitive Skin Care little ones

DRUG FACTS:

Active ingredient

Zinc oxide (20%)

Purpose

Sunscreen

Uses

- Helps prevent sunburn - If used as directed with other sun protection measures (see **Directions**), decreases the risk of skin cancer and early skin aging caused by the sun.

Warnings

For external use only. **Do not use** on damaged or broken skin. If rash occurs, stop use and ask a doctor. **When using this product** keep out of eyes. Rinse with water to remove.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Apply liberally 15 minutes before sun exposure - Reapply: - At least every 2 hours - After 40 minutes of swimming or sweating - Immediately after towel drying - **Sun Protection Measures:** Spending time in the sun increases your risk of skin cancer and early skin aging - To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including: - Limit time in the sun, especially from 10am-2pm - Wear long-sleeved shirts, pants, hats, and sunglasses - Ask a doctor for use on children under 6 months of age.

Inactive or non-medicinal ingredients

Aqua, caprylic/capric triglyceride, cetearyl alcohol, cetearyl glucoside, avena sativa (oat) kernel flour, glyceryl isostearate, glyceryl stearate, C10-18 triglycerides, glycerin, polyhydroxystearic acid, ethylhexylglycerin, caprylyl glycol, xanthan gum, sodium gluconate.

Other Information

Store at temperatures below 90°F.

PRINCIPAL DISPLAY PANEL - 75 g Tube Label

BIO SPECTRA

ATTITUDE®

little ones

SENSITIVE SKIN CARE

WORRY-FREE

• INGREDIENTS •

SPF

30

100% MINERAL

SUNSCREEN

BROAD SPECTRUM (UVA/UVB), NON NANO

HYPOALLERGENIC • FRAGRANCE-FREE

ACCEPTED

NATIONALECZEMA.ORG

NATIONAL

Eczema

ASSOCIATION

NPN 80047088

75 g / 2.6 OZ.

© 2018 BIO SPECTRA, MONTREAL, CANADA H2T 2A4 • 231, RUE SAINT-HONORE, PARIS, FRANCE 75001 / T: +33 (0)1 77 75 97 03 • MADE IN CANADA / FAIT AU CANADA

DRUG FACTS / RENSEIGNEMENTS

Active ingredient / Ingrédient médicinal Purpose / Utilisation
 Zinc oxide / Oxyde de zinc (20%).....Sunscreen / Crème solaire

Uses : ■ Helps prevent sunburn ■ If used as directed with other sun protection measures (see Directions), decreases the risk of skin cancer and early skin aging caused by the sun.
Utilisation : ■ Aide à prévenir les coups de soleil ■ Si utilisé selon le mode d'emploi et avec d'autres mesures de protection (voir Mode d'emploi), diminue les risques de cancer de la peau et de vieillissement prématuré de la peau.

Warnings / Attention :
For external use only. / Pour usage externe seulement.
Do not use on damaged or broken skin. If rash occurs, stop use and ask a doctor.
Ne pas utiliser sur la peau endommagée ou présentant des lésions. En présence d'une éruption cutanée, cesser l'utilisation et consulter un professionnel de la santé.
When using this product keep out of eyes. Rinse with water to remove.
Éviter tout contact avec les yeux. Rincer à l'eau le cas échéant.
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away. / **Garder hors de portée des enfants.** En cas d'ingestion, consulter un médecin immédiatement ou appeler un centre antipoison.

Directions: ■ Apply liberally 15 minutes before sun exposure ■ Reapply ■ At least every 2 hours ■ After 40 minutes of swimming or sweating ■ Immediately after towel drying ■ **Sun Protection Measures :** Spending time in the sun increases your risk of skin cancer and early skin aging ■ To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including: ■ Limit time in the sun, especially from 10am-2pm ■ Wear long-sleeved shirts, pants, hats, and sunglasses ■ Ask a doctor for use on children under 6 months of age.
Mode d'emploi : ■ Appliquer généreusement et uniformément 15 minutes avant l'exposition au soleil. ■ Appliquer de nouveau ■ au moins toutes les 2 heures. ■ Utiliser un écran solaire résistant à l'eau lors d'une activité aquatique ou s'il y a transpiration. ■ **Mesures de protection contre le soleil :** Passer du temps au soleil augmente le risque de cancer de la peau et de vieillissement prématuré de la peau. ■ Afin de diminuer ce risque, il convient d'utiliser régulièrement un écran solaire avec un F.P.S. à large spectre d'au moins 15 et d'appliquer d'autres mesures de protection contre le soleil, telles que : ■ limiter le temps passé au soleil, notamment entre 10 et 14 heures; ■ et porter des chemises à manches longues, des pantalons, un chapeau et des lunettes de soleil. ■ Pour les enfants âgés de moins de 6 mois, consulter un professionnel de la santé.

Inactive or non-medicinal ingredients / Ingrédients non médicinaux :
 Aqua, caprylic / capric triglyceride, cetearyl alcohol, cetearyl glucoside, avena sativa (oat) kernel flour, glyceryl isostearate, glyceryl stearate, C10-18 triglycerides, glycerin, polyhydroxystearic acid, ethylhexylglycerin, caprylyl glycol, xanthan gum, sodium gluconate.

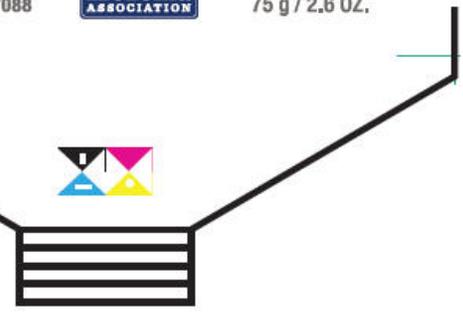
Other Information / Autre information :
 Store at temperatures below 90°F. / Entreposer à une température inférieure à 32°C.



100% MINERAL SUNSCREEN **SPF F.P.S. 30**
 BROAD SPECTRUM (UVA/UVB), NON NANO
 HYPOALLERGENIC · FRAGRANCE-FREE

CRÈME SOLAIRE 100% MINÉRALE
 LARGE SPECTRE (UVA/UVB), NON NANO
 HYPOALLERGÉNIQUE · SANS FRAGRANCE

NPN 80047088  75 g / 2.6 OZ.



ATTITUDE MINERAL SUNSCREEN SENSITIVE SKIN CARE LITTLE ONES			
zinc oxide cream			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61649-003
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength

ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	20 g in 100 g
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Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)	
OATMEAL (UNII: 8PI54V663Y)	
GLYCERYL ISOSTEARATE (UNII: HYE7O27HAO)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
C10-18 TRIGLYCERIDES (UNII: 43AGM4PHPI)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
XANTHAN GUM (UNII: TTV12P4NEE)	
SODIUM GLUCONATE (UNII: R6Q3791S76)	

Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61649-003-75	1 in 1 CARTON	02/01/2017	
1		75 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	02/01/2017	

Labeler - Bio Spectra (201137051)

Establishment

Name	Address	ID/FEI	Business Operations
Fusion Solution inc		251948899	MANUFACTURE(61649-003)